

REMARKS

This Application has been carefully reviewed in light of the Final Office Action dated July 21, 2008 (the "*Final Office Action*") and in view of the Advisory Action dated October 15, 2008 (the "*Advisory Action*"). At the time of the *Final Office Action*, Claims 40-44, 46-57, 62, 63, and 65-70 were pending of which Claims 40-44, 46-57, 62, 63, and 65-70 were rejected. Applicants have amended Claims 44, 52, 53, 67, and 70 and respectfully request reconsideration and favorable action in this case.

Section 112 Rejections of Claims 40, 44, 46, 48, 55-57, 62-63 and 65-70

The Examiner rejects Claims 40, 44, 46, 48, 55-57, 62-63 and 65-70 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner further rejects Claims 41-43, 45-54, 56-57, 62-63, and 65-70 under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully traverse these rejections for the reasons stated below.

With respect to Claims 40, 44, 46, 48, 55, 67, and 70, the Examiner asserts that the specification does not have support for "a substantially constant thread height." More particularly, the Examiner contends that "applicant does not have support for the term 'substantially' which broadens the dimensions to a range such that adjacent threads may have slightly different dimensions." See *Final Office Action*, page 5, lines 1-5. However, in the Office Action of January 28, 2008 the Examiner objected to the drawings because they did not illustrate a constant thread height, but rather "a tapered thread height." See January 28, 2008 Office Action, page 3, lines 1-2. Applicants respectfully remind the Examiner that "[a]n applicant may show possession of an invention by disclosure of drawings." M.P.E.P. § 2163. Thus, because there is support in the specification for: (1) a "tapered thread height;" and (2) a constant thread height and thread pitch (See *Final Office Action*, page 5, line 2), there is necessarily support for a "*substantially constant* thread height and pitch. See M.P.E.P. § 2173.07(a) ("[b]y disclosing in a patent application a device that inherently has . . . a property . . . a patent application necessarily disclose that function, theory or advantage, even though it says nothing explicitly concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter."). Further, Applicants respectfully submit that one of ordinary skill in the art would appreciate that Applicant's specification supports substantially constant physical characteristics (e.g.,

thread pitch and thread height) that may result due to, for example, manufacturing imperfections or tolerances. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claims 40, 44, 46, 48, 55, 67, and 70 under 35 U.S.C. § 112, first paragraph.

Regarding Claims 40, 55, 67, and 70 and various of their respective dependent claims (Claims 56-57, 62-63, 65-66, and 68-69), the Examiner contends that the limitation “configured to *fit precisely* into a sinus tarsi’ is considered new matter.” *See Final Office Action*, page 5, lines 6-10. To advance prosecution, Applicants amended Claims 40, 55, 67, and 70 such that each of said claims includes limitations generally directed to a body that is configured to fit snugly in into a sinus tarsi. The Examiner’s comments in the *Advisory Action* indicate that these amendments were sufficient to overcome the rejections. Accordingly, Applicants respectfully request the Examiner to withdraw the associated rejections of Claims 40, 55-57, 62-62, and 65-70 under 35 U.S.C. § 112, first paragraph.

With respect to Claim 41-43 and 46-54, the Examiner contends that Claim 41 has improper dependency. *See Final Office Action*, page 5, lines 17-18. In response, Applicants have amended Claim 41 to depend from Claim 40. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claim 41-43 and 46-54 under 35 U.S.C. § 112, second paragraph.

With respect to Claims 41, 56, 67, and 70 and various of their respective dependent claims (Claims 42-43, 46-54, 57, 62-66, and 68-69), the Examiner contends that the limitations, “the leading flank separated by [sic] the trailing flank by a thread angle” is indefinite and unclear. *See Final Office Action*, page 5, lines 19-20. To advance prosecution, Applicants have amended Claims 41, 56, 67, and 70 to clarify that the leading flank and the trailing flank define a thread angle. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claim 41-43 and 46-54, 56-57, and 62-70 under 35 U.S.C. § 112, second paragraph.

Section 102 Rejections

The Examiner rejects Claims 40, 41, 52, 53, 55, 56, 62, and 66 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,607,304 ("*Bailey*"). The Examiner further rejects Claims 40, 41, 47, 50, 52-56, 62, 63, 66, and 70 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,683,460 to Persoons ("*Persoons*"). Applicants respectfully traverse these rejections for the reasons stated below.

I. Neither *Bailey* nor *Persoons* disclose a body configured to fit snugly into a sinus tarsi as generally required by Claims 40, 55, and 70.

Applicants respectfully submit that both *Bailey* and *Persoons* fail to disclose, or even teach or suggest, the elements specifically recited in Applicants' claims. For example, *Bailey* and *Persoons* fail to disclose, teach, or suggest the following elements recited in independent Claim 40:

A medical implant, comprising:

a body **configured to fit snugly** into a sinus tarsi of a subtalar joint in a human foot,

To reject these limitations, the Examiner does not point to any support in either *Bailey* or *Persoons*, but rather conclusorily states (1) that *Bailey's* alleged medical implant is "capable of placement at such location to fit between bones" and (2) that *Persoons'* medical implant is "capable of placement at such location and capable of such a fit as Persoon's [sic] device is relatively small and intended for use between bones to act as a spacer." See *Final Office Action* page 6, line 12, page 7, line 4. Applicants respectfully disagree with these rejections.

With regard to *Bailey*, the Examiner identifies a shaft portion of "abutment 16" as the body of Claim 1. *Final Office Action* page 6, line 11. With regard to *Persoons*, the Examiner identifies a "body 102" as the body of Claim 1. *Final Office Action* page 7, line 3. In general, Applicants do not necessarily agree with the Examiner's identifications but refer to them for the sake of argument. Respectfully, nothing in the entirety of either *Bailey* or *Persoons* discloses that the alleged bodies described therein are "configured to fit **snugly** into a sinus tarsi" as required by Claim 40. Moreover, the Examiner's argument that the alleged bodies of *Bailey* and *Persoons* are "capable of" fitting in a sinus tarsi does not address the requirements of a snug fit.

Consequently, at a minimum, both *Bailey* and *Persoons* fail to disclose, teach, or suggest “a body **configured to fit snugly** into a sinus tarsi” of independent Claim 40. For at least these reasons, Applicants respectfully request the Examiner to withdraw the rejection of independent Claim 40 and its dependent claims under 35 U.S.C. § 102. For analogous reasons, independent Claims 55, and 70 and their respective dependent claims are allowable under 35 U.S.C. § 102. Furthermore, Applicants contend that the above-presented arguments apply with equal force to distinguish these claims from further rejections under 35 U.S.C. § 103 presented by the Examiner below based on the same art.

II. Neither *Bailey* nor *Persoons* disclose a thread configured to limit pain as generally required by Claim 52.

Applicants further contend that neither *Persoons* nor *Bailey* disclose, or even teach or suggest, the following elements recited in Claim 52:

the thread is configured to secure the body into the sinus tarsi, and to **limit pain** caused to a patient by the thread once the medical implant is inserted into the sinus tarsi

In the *Final Office Action*, the Examiner did not address these limitations. Applicants respectfully remind the Examiner, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). For these additional reasons, Applicants respectfully contend that Claim 52 is allowable under 35 U.S.C. § 102.

III. *Persoons* does not disclose a leading flank or a tailing flank as required by Claims 41, 56, and 70.

Applicants further contend that *Persoons* does not disclose, or even teach or suggest, the following elements recited in Claim 41:

the thread includes a leading flank **inclined away from the second end** and spanning from the crest to a thread root and a trailing flank **inclined away from the first end** and spanning from the crest to the thread root, the leading flank and the trailing flank defining a thread angle.

The Examiner relies on the passage of *Persoons* at Col. 3, lines 23-25 to teach these elements. According to the passage:

Body 2 bears a blocking member in the form of a helical thread 5 protruding radially from body 2. Thread 5 has a non-cutting, blunt or flat edge. The **head 3 is separated from the collar 7 by a steep edge** while the generating line of the helical thread 5 is substantially perpendicular to the longitudinal axis of the body 2.

That is, the passage discloses that a “steep edge” separates head 3 from collar 7. Applicants respectfully point out that this statement does not involve the alleged thread of *Persoons* but rather the separation between head 3 and collar 7. In fact, nothing in *Persoons* a thread that includes leading flank **inclined away from the second end** a trailing flank **inclined away from the first end**. For these additional reasons, Applicants further respectfully request the Examiner to withdraw the rejection of Claim 41 and its dependent claims based upon *Persoons* under 35 U.S.C. § 102. For analogous reasons, Applicants respectfully request the Examiner to withdraw the rejections of Claims 56, and 70 and their respective dependent claims with respect to *Persoons* under 35 U.S.C. § 102.

Section 103 Rejections

The Examiner rejects Claims 43, 46, 48, 49, 50, 51, and 65 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Bailey*. The Examiner rejects Claims 40, 41, 43, 50, 52, 53, 55, 56, 62, and 66 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,961,524 to Crombie (“*Crombie*”). The Examiner rejects Claims 42, 44, and 57 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Persoons* in view of U.S. Patent No. 5,951,560 to Simon et al. (“*Simon*”). The Examiner rejects Claims 67-70 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Publication No. 2004/0097928 A1 by Zdeblick et al. (“*Zdeblick*”) in view of U.S. Patent No. 5,897,593 to Kohrs et al. (“*Kohrs*”). Applicants respectfully traverse these rejections for the reasons stated below.

IV. *Crombie* does not disclose, teach, or suggest “a body configured to fit snugly into a sinus tarsi” as generally required by Claims 40 and 55.

As mentioned above, Claim 40 is directed, in part, to a medical implant having “a body configured to fit **snugly** into a sinus tarsi of a subtalar joint in a human foot.” To reject these limitations, the Examiner does not point to any support in *Crombie*, but rather identifies an “entire screw 10” as the body of Claim 40 and conclusorily states that *Crombie*’s screw 10 is “capable of placement at such a location and due to its disclosed wide variation of shape/size, it is capable of precise fit.” Applicants respectfully disagree with this rejection.

Applicants respectfully point out that the Examiner is arguing that the entire screw 10 of *Crombie* (including a head) is configured to fit into a sinus tarsi of a human foot. The entire screw 10 of *Crombie* is **not** configured to fit snugly into a sinus tarsi at least because screw 10 includes a screw head that would cause an uncomfortable pressure point in the sinus tarsi. For example, Applicant's specification states that localized pressure points between the implant and the surrounding bones may cause pain or even result in the implant popping out of the sinus tarsi. See Specification, page 9.

Consequently, at a minimum, *Crombie* fails to disclose, teach, or suggest "a body configured to fit **snugly** into a sinus tarsi" of Claim 40. Thus, combination of *Crombie* with the knowledge of one of ordinary skill in the art as proposed by the Examiner fails to disclose, teach, or suggest the elements of independent Claim 40. For at least these reasons, independent Claim 40 and its dependent claims are allowable under 35 U.S.C. § 103. For analogous reasons, independent Claims 55 and its respective dependent claims are allowable under 35 U.S.C. § 103.

V. *Persoons* does not disclose, teach, or suggest "a body adapted for implantation into a sinus tarsi" as generally required by Claims 44 and 55.

Applicants further contend that *Persoons* does not disclose, or even teach or suggest, the following elements recited in Claim 44:

a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot;

To reject these limitations, the Examiner does not cite to a passage of *Persoons* but rather states "*Persoon's* [sic] discloses a medical implant and method of forming a medical implant substantially as claimed." See *Final Office Action*, page 9, lines 12-13. Applicants respectfully disagree. According to *Persoons*:

The present invention relates to an intrafocal peg for stabilization and osteosynthesis of a **fracture in the wrist**.

See *Persoons*, Col. 1, lines 6-7. Consequently, at a minimum, *Persoons* fails to disclose, teach, or suggest "a body **adapted for implantation into a sinus tarsi** of a subtalar joint in a human foot" of Claim 44. Thus, combination of *Persoons* and *Simon* proposed by the Examiner fails to disclose, teach, or suggest the elements of independent Claim 44. For at

least these reasons, independent Claim 44 and its dependent claims are allowable under 35 U.S.C. § 103.

VI. Neither *Zdeblick* nor *Kohrs* disclose, teach, or suggest a thread configured to limit pain as generally required by Claim 67.

Applicants further contend that Persoon's does not disclose, or even teach or suggest, the following elements recited in Claim 67:

the thread is configured to secure the body into the sinus tarsi, and to **limit pain** caused to a patient by the thread once the body is inserted into the sinus tarsi

As discussed with respect to Claim 52 above, the Examiner did not address these limitations in the *Final Office Action*. Applicants respectfully remind the Examiner that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Accordingly, Applicants respectfully contend that neither *Zdeblick* nor *Kohrs* disclose, teach, or suggest these limitations. For at least these reasons, independent Claim 67 and its dependent claims are allowable under 35 U.S.C. § 103. For analogous reasons, independent Claims 70 is allowable under 35 U.S.C. § 103.

No Waiver

Applicants have merely discussed example distinctions from the references cited by the Examiner. Other distinctions may exist, and Applicants reserve the right to discuss these additional distinctions in a later Response or on Appeal, if appropriate. By not responding to additional statements made by the Examiner, Applicants do not acquiesce to the Examiner's additional statements. The example distinctions discussed by Applicants are sufficient to overcome the Examiner's rejections.

All Claims Are in Condition for Allowance

For at least the reasons explained above, Applicants respectfully contend that each and every one of the claims of the instance Application are in condition for allowance.

CONCLUSION

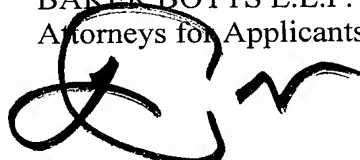
Applicants have now made an earnest attempt to place this case in condition for immediate allowance. For the foregoing reasons and for other apparent reasons, Applicants respectfully request full allowance of all pending claims.

If the Examiner feels that a telephone conference or an interview would advance prosecution of this Application in any manner, please feel free to contact the undersigned attorney for Applicants.

The Commissioner is hereby authorized to charge the **\$810.00 RCE fee**, and to the extent necessary, charge any additional fees or credit any overpayments to **Deposit Account No. 02-0384 of BAKER BOTTS L.L.P.**

Respectfully submitted,

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